**Proposed Revisions to**
**Division of Medical Assistance N.C. Prior Authorization Program**
**Botulinum Toxins (Type A and Type B) Effective Date:**
**DRAFT**

**Therapeutic Class Code:** S7A

**Therapeutic Class Description:** Neuromuscular Blocking Agents

| Medication | Generic Code Number(s) |
|---|---|
| Botox (Botulinum Toxin Type A) | 23360 |
| Myobloc (Botulinum Toxin Type B) | 12245, 12246, 12247 |

## Early Periodic Screening, Diagnostic and Treatment Provision

Early Periodic Screening, Diagnostic and Treatment (EPSDT) allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary health care services to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service product or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** Additional information on EPSDT guidelines may be access at http://www.ncdhhs.gov/dma/EPSDTprovider.htm.

## Criteria

### Botulinum Toxin Type A (Botox)

Medicaid covers botulinum toxin type A (Botox) for the following conditions:

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia patients in whom surgical treatment is not indicated
- Blepharospasm
- Spasmodic torticollis, secondary to cervical dystonia
- Hereditary spastic paraplegia
- Multiple sclerosis for patients with spasticity
- Schilder's disease
- Neuromyelitis optica for patients with spasticity secondary to spinal cord involvement
- Other demyelinating diseases of central nervous system with secondary spasticity
- Spastic hemiplegia/quadriplegia and hemiparesis affecting dominant side
- Spastic hemiplegia/quadriplegia and hemiparesis affecting non-dominant side
- Congenital diplegia—Infantile hemiplegia

- Infantile cerebral palsy, specified or unspecified
- Disorders of eye movement (strabismus)
- Laryngeal spasm
- Achalasia and cardiospasm
- Gustatory hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Primary focal hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met:
  - The patient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
  - There is documentation that the patient has failed a 6-month trial of conservative management, including the use of topical aluminum chloride or extra-strength antiperspirant.

**Botulinum Toxin Type B (Myobloc)**

Medicaid covers botulinum toxin type B (Myobloc) for the following conditions:

- Sialorrhea
- Spasmodic torticollis, secondary to cervical dystonia

There are several botulinum toxins, currently A through G. Only A and B are now FDA-approved and commercially available. This policy deals *only* with botulinum toxin A (Botox) and botulinum toxin B (Myobloc). These share certain properties, and some FDA approvals, as well as certain off-label uses that are addressed in this policy. However, these two agents are *not* identical, and have differing therapeutic and adverse event profiles. Furthermore, units and dosing are not equivalent, so they are not directly interchangeable with one another. It is expected that physicians familiar with and experienced in use of these agents will utilize evidence-based medicine to select the appropriate drug and dose regimen for each patient, condition, and use.

**Procedures**

1. Not approved for cosmetic purposes
2. Approval length up to 12 months
3. Dosage limitations for botulinum toxin Type A (Botox): the cumulative dosage should not exceed 600 units in 90 days.
4. Dosage limitations for botulinum toxin Type B (Myobloc): 10,000 units in 12 weeks (3 months).

## References

1. Lim M, Mace A, Nouraei SA, Sandhu G. Botulinum toxin in the management of sialorrhoea: a systematic review. Clin Otolaryngol. 2006 Aug;31(4):267-72.
2. Allergan Pharmaceuticals, Inc. Botox package insert. Irvine (CA); Revised October 2004.
3. Solstice Neurosciences, Inc. Myobloc package insert. South San Francisco (CA); Revised November 2004.
4. Cheng CM, Chen JS, Patel RP. Unlabeled Uses of Botulinum Toxins: A Review, Part 1. Am J Health-Syst Pharm. 2005; 63(2):145-152. Accessed through http://www.medscape.com on February 6, 2006.
5. Cheng CM, Chen JS, Patel RP. Unlabeled Uses of Botulinum Toxins: A Review, Part 2. Am J Health-Syst Pharm. 2006; 63(3):225-232. Accessed through http://www.medscape.com on March 8, 2006.
6. Sycha T, Kranz G, Auff E, Schnider P. Botulinum toxin in the treatment of rare head and neck pain syndromes: a systematic review of the literature. J Neurol (2004) 251 [Suppl 1]; I/19-I/30.
7. Wasiak J, Hoare B, Wallen M. Botulinum toxin A as an adjunct to treatment in the management of the upper limb in children with spastic cerebral palsy. The Cochrane Database of Systematic Reviews 2004, Issue 4. Art. No.: CD003469.pub3. DOI: 10.1002/14651858.CD003469.pub3.
8. North Carolina State Health Plan. Clostridium Botulinum Neurotoxins. Medco Health Solutions, April 2005.